



## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2022-0918; FRL-10490-02-OCSPP]

### Cumulative Risk Assessment; Science Advisory Committee on Chemicals (SACC) Virtual Public Meeting; Notice of Availability and Request for Comment

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** The Environmental Protection Agency (EPA) is announcing the availability of and soliciting public comment on two draft documents that are being submitted to the Science Advisory Committee on Chemicals (SACC) for peer review: “Draft Proposed Principles of Cumulative Risk Assessment under the Toxic Substances Control Act” and “Draft Proposed Approach for Cumulative Risk Assessment of High-Priority Phthalates and a Manufacturer-Requested Phthalate under the Toxic Substance Control Act.” The SACC will consider and review these documents at a 4-day virtual public meeting on May 8 to 11, 2023, that was previously announced in the *Federal Register* of December 21, 2022.

**DATES:** The following is a chronological listing of the dates for the specific activities that are described in more detail under **SUPPLEMENTARY INFORMATION**.

April 24, 2023 – Deadline for submitting a request for special accommodations for participating in the virtual public meeting in order to allow EPA time to process the request before the meeting.

[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] – Deadline for providing comments for distribution to the SACC before the meeting.

May 1, 2023 – Deadline for registering to be listed on the meeting agenda to make oral comments during the virtual meeting. Those not making oral comments may continue to register through May 11, 2023 in order to receive the links to observe the meeting.

**ADDRESSES:** Submit written comments, identified by docket identification (ID) number EPA-HQ-OPPT-2022-0918, through the Federal eRulemaking Portal at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not electronically submit any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Copyrighted material will not be posted without explicit permission from the copyright holder. Members of the public should also be aware that personal information included in any written comments may be posted on the internet at <https://www.regulations.gov>. Additional information on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

For information on how to register and access the virtual public meeting, please refer to the SACC website at <https://www.epa.gov/tsca-peer-review>. EPA intends to announce registration instructions on the SACC website by early April 2023. You may also subscribe to the following listserv for alerts regarding this and other SACC-related activities: [https://public.govdelivery.com/accounts/USAEPAPPT/subscriber/new?topic\\_id=USAEPAPPT\\_101](https://public.govdelivery.com/accounts/USAEPAPPT/subscriber/new?topic_id=USAEPAPPT_101).

For information on special accommodations, meeting access or services for individuals with disabilities, and to request accommodation for a disability, please contact the Designated Federal Officer (DFO) listed under **FOR FURTHER INFORMATION CONTACT**.

**FOR FURTHER INFORMATION CONTACT:** Contact the DFO, Dr. Alaa Kamel, Mission Support Division (7602M), Office of Program Support, Office of Chemical Safety and Pollution Prevention, EPA, telephone number: (202) 564-5336 or call the SACC main office at (202) 564-8450; email address: [kamel.alaa@epa.gov](mailto:kamel.alaa@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this action apply to me?*

This action is directed to the public in general.

*B. What action is the Agency taking?*

EPA is announcing the availability of and soliciting public comment on the following two draft documents that are being submitted to the Science Advisory Committee on Chemicals (SACC) for peer review: “Draft Proposed Principles of Cumulative Risk Assessment under the Toxic Substances Control Act” and “Draft Proposed Approach for Cumulative Risk Assessment of High-Priority Phthalates and a Manufacturer-Requested Phthalate under the Toxic Substance Control Act.” The SACC will consider and review these documents at a 4-day virtual public meeting on May 8 to 11, 2023, which was previously announced in the *Federal Register* of December 21, 2022 (87 FR 78103 (FRL-10490-01-OCSPP)).

This document provides instructions for accessing the materials provided to the SACC, submitting comments, and registering to provide oral comments at the meeting.

*C. What is the Agency's authority for taking this action?*

The SACC was established by EPA in 2016 in accordance with the Toxic Substances Control Act (TSCA), 15 U.S.C. 2625(o), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, Public Law 114-182, June 22, 2016, to provide independent advice and expert consultation, at the request of the Administrator, with respect to the scientific and technical aspects of issues relating to the implementation of TSCA. The SACC operates in accordance with the Federal Advisory Committee Act (FACA), 5 U.S.C. 10 *et seq.*, and supports activities under the TSCA, 15 U.S.C. 2601 *et seq.*, the Pollution Prevention Act (PPA), 42 U.S.C. 13101 *et seq.*, and other applicable statutes.

*D. What should I consider as I submit my comments to EPA?*

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email (contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** for instructions). Clearly mark the part or all of the information that you claim to be CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with

procedures set forth in 40 CFR part 2.

2. *Tips for preparing comments.* When preparing and submitting your comments, see Tips for Effective Comments at <https://www.epa.gov/dockets>.

## **II. Background**

### *A. What is the purpose of the SACC?*

The SACC provides independent scientific advice and recommendations to the EPA on the scientific and technical aspects of risk assessments, methodologies, and pollution prevention measures and approaches for chemicals regulated under TSCA. The SACC is composed of experts in toxicology; environmental risk assessment; exposure assessment; and related sciences (e.g., synthetic biology, pharmacology, biotechnology, nanotechnology, biochemistry, biostatistics, physiologically based pharmacokinetic modeling (PBPK), computational toxicology, epidemiology, environmental fate, and environmental engineering and sustainability). The SACC currently consists of 17 members. When needed, the committee will be assisted by *ad hoc* peer reviewers with specific expertise in the topics under consideration.

### *B. Why did EPA develop these documents?*

Between 2020 and 2022, EPA published final scoping documents for 20 High-Priority and three Manufacturer-Requested chemical substances for risk evaluation under TSCA. During the scoping process, EPA received comments from stakeholders urging the Agency to consider evaluating several chemical substances undergoing risk evaluation for cumulative risk to human health. TSCA does not explicitly require EPA to conduct cumulative risk assessments (CRAs). However, TSCA does require EPA to consider the reasonably available information and to use the best available science and to make decisions based on the weight of scientific evidence [15 U.S.C. 2625(h), (i), (k)]. EPA recognizes that for some chemical substances, the best available science may indicate that the development of a CRA is appropriate to ensure that any risks to human health and the environment are adequately characterized.

EPA's document entitled "Draft Proposed Principles of Cumulative Risk Assessment

under the Toxic Substances Control Act” describes the fundamental principles of CRA of chemical substances and how they may be applied within the regulatory requirements of TSCA to ensure TSCA risk evaluations are based on the best available science and are protective of human health. This draft document, a copy of which is being submitted to the SACC for review and is available in the docket for public review, is not a framework nor a guidance document on conducting CRAs of chemical substances, and it does not address cumulative impacts.

Recognizing that human exposure to phthalates is widespread and that multiple phthalates can disrupt development of the male reproductive system in laboratory animals at potentially human relevant doses, EPA asked the National Research Council (NRC) of the National Academies of Science to review the health effects of phthalates and determine whether a cumulative risk assessment of phthalates should be conducted, and if so, what approaches could be used for the assessment. In 2008, NRC published their findings to EPA in a final report entitled “Phthalates and Cumulative Risk Assessment: The Task Ahead” (a copy can be accessed at [https://cfpub.epa.gov/si/si\\_public\\_record\\_report.cfm?Lab=NCEA&dirEntryId=202508](https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=NCEA&dirEntryId=202508)). In that report, the NRC recommended that a cumulative risk assessment should be conducted for phthalates. EPA’s document entitled “Draft Proposed Approach for Cumulative Risk Assessment of High-Priority Phthalates and a Manufacturer-Requested Phthalate under the Toxic Substance Control Act” describes EPA’s proposed approach for evaluating a subset of High-Priority and Manufacturer-Requested phthalates for cumulative risk to human health under TSCA based on the principles of CRA described in EPA’s draft principles document referenced previously. EPA’s draft proposed approach follows many of the recommendations made by the NRC in 2008. This draft document, a copy of which is being submitted to the SACC for review and is available in the docket for public review, is not a CRA, and no risk estimates are presented. Instead, this draft document outlines several options EPA is considering for conducting a phthalate CRA under TSCA.

In submitting these two draft documents to the SACC for peer review, EPA is soliciting

comments from the SACC on issues related to chemical grouping for purposes of CRA, health outcomes related to phthalate syndrome, and possible approaches to developing the cumulative hazard and exposure assessment for High-Priority phthalates and a Manufacturer-Requested phthalate.

### **III. Virtual Public Meeting**

#### *A. What is the purpose of this public meeting of the SACC?*

The focus of the 4-day virtual public meeting is the SACC peer review of the following two draft documents and related public comments received by the deadlines listed under the **DATES** section:

- Draft Proposed Principles of Cumulative Risk Assessment under the Toxic Substances Control Act; and
- Draft Proposed Approach for Cumulative Risk Assessment of High-Priority Phthalates and a Manufacturer-Requested Phthalate under the Toxic Substance Control Act.

EPA *will* provide a meeting agenda for each day of the meeting, and, as needed, may provide updated times for each day in the meeting agenda that will be posted in docket and on the SACC website.

#### *B. How can I access the documents submitted for review to the SACC?*

These documents, including background documents, related supporting materials, and draft charge questions provided to the SACC, are available in the docket. As additional background materials become available and are provided to the SACC, EPA will include those additional background documents in the docket. All of these documents will be available through <https://www.regulations.gov> in Docket ID No. EPA-HQ-OPPT-2022-0918 and links on the SACC website at <https://www.epa.gov/tsca-peer-review>.

After the public meeting, the SACC will prepare a meeting minutes and final report document summarizing its recommendations to the EPA. This document will also be added to the docket and available through the SACC website.

*C. How can I provide comments for the SACC's consideration?*

To ensure proper receipt of comments by EPA, it is imperative that you identify Docket ID No. EPA-HQ-OPPT-2022-0918 in the subject line on the first page of your comments and follow the instructions in this unit.

1. *Written comments.* Written comments must be submitted by the deadlines set in the **DATES** section and following the instructions in this document.

2. *Oral comments.* Each individual or group wishing to make brief oral comments to the SACC during the peer review virtual public meeting must register to do so by the deadline set in the **DATES** section and following the registration instructions that will be announced on the SACC website by early April 2023. Oral comments will be limited to 5 minutes. In addition, each speaker should submit a copy of their comments to the DFO prior to the meeting for distribution to the SACC by the DFO and inclusion in the docket.

*D. How can I participate in the virtual public meeting?*

The virtual public meeting will be held via a webcast platform such as “Zoom.gov” and audio teleconference. You must register online to receive the webcast meeting link and audio teleconference information. Please follow the registration instructions that will be announced on the SACC website in April.

**Authority:** 15 U.S.C. 2625(o); 5 U.S.C 10 *et. seq.*

**Dated:** February 22, 2023.

**Michal Freedhoff,**

*Assistant Administrator, Office of Chemical Safety and Pollution Prevention.*

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